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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,596	02/09/2001	Jean-Richard Neeser	88265-406	6562

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,596

Applicant(s)

NEESER ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7,9,10 and 23-38 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 29-38 is/are allowed.
6) ☒ Claim(s) 1,3,4,6,7,9,10 and 23-28 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on May 5, 2004), Applicants filed a response and amendment received on October 7, 2004. Said amendment amended Claims 1, 3, 6, 10, and 25-29 and added new Claims 30-38. Thus, Claims 1, 3, 4, 6, 7, 9, 10, and 23-38 are pending in the instant Office action and will be examined herein.

Priority

2. Receipt is acknowledged of papers (EP 98202707.0) submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Thus, the instant application is granted the benefit of priority for the foreign application 98202707.0 filed in Europe on December 8, 1998 as requested in the declaration. Priority is also granted, as previously noted, to the parent application, PCT/EP99/05473 filed on July 26, 1999.

Withdrawn – Objections to the Specification

3. Previous objection to the specification for the confusions with respect to GenBank Numbers and/or FUM media is withdrawn by virtue of Applicant's amendment.

New – Objections to the Specification

4. The amendment filed October 7, 2004 is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not

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supported by the original disclosure is as follows: the Gmur *et al.* reference to FUM media.

Applicant is required to cancel the new matter in the reply to this Office Action.

The Examiner notes that this insertion into the specification was in direct response to the Examiner's objection to the term "FUM medium" on page 14. The Examiner was unaware that support for this reference was not found elsewhere in the specification (no support has been cited by Applicant nor can the Examiner identify support). Removal of the reference for the purpose of obviating the instant objection will *not* reinstate the objection to the specification as the record clearly includes the appropriate reference and the specification cannot without containing new matter.

Withdrawn - Objections to the Claims

5. Previous objection to Claim 10 for having a typographical error is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

6. Previous rejection Claims 6 and 25-26 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "about" with respect to a temperature or a weight percent is withdrawn by virtue of Applicant's amendment removing the term.

Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

7. Previous rejection of Claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "of dairy origin" is maintained and altered to the amended term used by Applicant, "originally derived from a dairy". Applicant's arguments have been fully considered

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but are not deemed persuasive. Applicant argues that the term is now clear because it indicates “the claim is directed to any lactic bacterium that is originally from a dairy regardless of whether and how many times the bacterium is genetically modified.” Firstly, the Examiner’s previous issues with the phrase are maintained as follows:

“As previously noted, the instant specification is replete with examples of recombinant DNA and strain technologies. Thus, in the field under which the instant application is filed, the term “dairy origin” requires clear definition. Must the lactic bacteria be naturally occurring? If not, how many alterations to a naturally occurring dairy lactic acid bacteria strain can be made before the strain is considered “of different origin”?”

If, as Applicant suggests, a bacteria, regardless of genetic modification, originally from dairy, then this limitation reads on any bacteria since entire genomes can be substituted with today’s recombinant technologies.

Additionally, the Examiner is unclear is the bacteria must now come from a dairy (i.e., a place that makes/sells milk and milk products) or if, as written, the bacteria must be “originally derived from a dairy”, which phrase is wholly unclear as to how a bacteria can be derived from a place. Clarification is required.

Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

8. Previous rejection of Claims 1, 3, 4, 6, 7, 9, 10, and 23-28 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive. Applicant argues that *Searle* is not applicable in the instant case because in *Searle* not a single example was set forth to satisfy written description in contrast to the instant case where several examples of lactic acid bacteria have been set forth to be used in the claimed methods. The Examiner disagrees that this distinction from *Searle* renders *Searle*,

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and *Enzo*, inapplicable. The point of *Searle* is to set forth that assessment of written description, as set forth by *Enzo*, i.e., (1) representative species and (2) correlation of structure and function from representative species to other members of the claimed genus, is applicable regardless of whether a method or the product, as was the case in *Enzo*, is being claimed. Thus, the combination of *Searle* and *Enzo* are well-applied to the instant claims.

Applicant further argues that the pH characteristics of the bacteria used in the claimed methods are enough to satisfy the structural requirement of written description; this is not the case. All the characteristics of the bacteria used in the claimed methods are functional ALONE. In fact, the bacteria were identified in a functional screening procedure so that no common structural characteristics are known and/or set forth by the instant specification.

Applicant further argues issues previously addressed; the Examiner's previous comments are, therefore, reiterated below:

“Applicant also argues that *Amgen*, and not *Lily*, is an appropriate precedent for the pending claims; the Examiner disagrees. In *Amgen* the written description of a characterized protein product from a specific DNA sequence being made in a mammalian cell is at issue as to whether two species of mammalian cell expression of the protein provides adequate written description for the genus of the protein being expressed in any mammalian cell. In the instant case, Applicant would have the five examples of specifically functioning lactic acid bacteria support the claimed genus of all lactic acid bacteria with this claimed function for use in the claimed methods wherein no correlation between structure and function is described. While equivalent protein expression of two mammalian cells can adequately describe the genus of proteins expressed in all mammalian cells, the subset of lactic acid bacteria for use in the claimed invention cannot without some indication of the correlating structure – a point specifically made in *Enzo Biochemical*.”

Applicant also argues, using *Enzo*, that “other physical and/or chemical properties” of the lactic acid bacteria of the claimed methods are sufficient for written description of the claimed

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genus since neither “complete or partial structure” or “functional characteristics when coupled with a known or disclosed correlation between function and structure” are disclosed for said lactic acid bacteria. However, the Examiner maintains that the physical and/or chemical properties of (1) not being present in the microflora of the human mouth, (2) providing a pH in the oral cavity of between 5.5 and 7, and (3) being capable of adhering directly to the pellicle of the teeth, which properties are the only properties taught and/or limited in the claims, provide adequate written description for the bacteria used in the claimed methods. No size, no genetic make-up (rRNA), no color, etc. are described for the bacteria. As such, the genus lacks adequate written description.

Summary of Pending Issues

9. The following is a summary of the issues pending in the instant application:
- a) The specification stands objected to for containing new matter.
 - b) Claim 3 stands objected to under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “originally derived from a dairy”.
 - c) Claims 1, 3, 4, 6, 7, 9, 10, and 23-28 stand rejected under 35 U.S.C. § 112, first paragraph, written description.

Conclusion

10. Claims 29-38 are allowed in the Office action; claims 1, 3, 4, 6, 7, 9, 10, and 23-28 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
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January 7, 2005